

0127 5 SEP 22 P2:19

Ortho Molecular Products Inc. 3017 Business Park Drive P.O. Box 1060 Stevens Point, WI 54481 715.342.9881 Phone 800.332.2351 715.342.9866 Fax orthomolecularproducts.com Office of Special Nutritional (HFS-450) Center for Food Safety and Applied Nutrition U.S. Food and Drug Administration 5100 Paint Branch Parkway College Park, MD 20740-3835

AUG -9 2005

Dear Sir/Madam:

This letter will serve as notification, pursuant to section 403 (r)(6) of the Federal Food, Drug, and Cosmetic Act and 21 CFR 101.93, that Ortho Molecular Products, Inc. is using the following claim on its label (see attached labels on page 2).

Name of Manufacturer: Ortho Molecular Products, Inc.

3017 Business Park Drive

P.O. Box 1060

Stevens Point, WI 54481

Statement Text: Cardiovascular Health

Dietary Ingredients: Policosanol (from Sugar Cane), Natural vegetable capsules, Ascorbyl Palmitate, Magnesium Stearate, Microcrystalline Cellulose, Silicon Dioxide.

Dietary Supplement Name: Policosanol

As required, enclosed are two photocopies of this notification.

I certify that the information presented and contained in this notice is complete and accurate, and that Ortho Molecular Products, Inc. has substantiation that the statement is truthful and not misleading.

Sincerely,

Melissa Slager

Document Control / Training Manager

Ortho Molecular Products

975 0162 LET 16625



Ortho Molecular Products Inc. 3017 Business Park Drive P.O. Box 1060 Stevens Point, WI 54481 715.342.9881 Phone 800.332.2351 715.342.9866 Fax orthomolecular products.com

Attachment of Policosanol Labels

Suggested Use: As a dietary supplement, 1 capsule per day or as recommended by your health care professional.

Formulated to be free of allergens derived from Gluten, corn, egg, dairy,
peanuts, soy, yeast, artificial colors and flavors. If you are pregnant, nursing or
using blood thinning medication, consult your physician before taking this product. As with all dietary supplements, some individuals may not betrate or may be
allege to the Ingredients used. Please read the ingredient panel carefully prior
to ingestion. Cesse taking this product and consult your physician if you have
negative reactions upon ingestion. This product was sealed for your purposition. On
tices if outer fogged neck seal or man-seal are missing or damaged.

Keep commarks marrix cosso. Since are now traversories (keep our or seal or or checken.)





Policosanol

Supplement Facts Serving Size 1 Capsule Servings Per Container. 60

Amount Per % Daily

Other Ingredients: Natural vegelable capsules. This product may contain one or more of the following: Ascorbyl Pallmitate, Magnessum Stearate, - Microscrystalline Cellulose and Silicon Dioxide.